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Box Patent Application
Commissioner of Patents and Trademarks
Washington, DC 20231

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NEW APPLICATION TRANSMITTAL

PATĖNT

Transmitted herewith for filing is the patent application of inventor:

First Name

Last Name

Residence

Citizenship

1. Horst

FÄRBER

For (title):

SAMPLING TUBE AND METHOD OF MAKING SAME

- 1. Type of Application
 - ✓ Utility
 - □ Design
 - □ Plant
 - ✓ Original
 - □ Divisional
 - □ Continuation
 - □ Continuation-in-part
- 2. Benefit of Prior US Application(s) (35 USC 120) or foreign priority (35 USC 119)
 - □ The new application being transmitted claims the benefit of a prior US application.
 - Foreign priority claimed (see ¶9)
- 3. Papers Enclosed Required For Filing Date Under 37 CFR 1.53(b) (Uti.) or 37 CFR 1.153 (Des.)
 - ✓ Pages of specification (10)
 - Pages of claims (2)
 - Pages of Abstract (1)
 - ✓ Sheets of Drawing (2)
 - ✓ Formal
 - □ Informal

4.	Additional	papers enclosed					
		Preliminary Amendment					
		Information Disclosure Statement					
		PTO-1449					
		Citations (none)					
		Declaration of Biological Deposit					
		Submission of "Sequence Listing," computer-readable copy and/or amendment pertaining					
		thereto for biotechnology invention containing nucleotide and/or amino-acid sequence					
	<u> </u>	Authorization of Attorney(s) to accept and follow instructions from Representative					
	໔	Other PTO Data Entry Form					
		ner					
5.	Declaration	or Oath					
		Enclosed					
		original executed by					
		□ Inventor(s)					
		legal representative of inventor(s). 37 CFR 1.42 or 1.43					
		joint inventor or person showing a proprietary interest on behalf of inventor who					
		refused to sign or could not be reached					
		this is the petition required by 37 CFR 1.47 and the statement required by 37					
		CFR 1.47 is also attached					
	Ø	Not Enclosed					
		Application is made by a person authorized under 37 CFR 1.41(c) on behalf of all the					
		above-named inventor(s).					
		□ Showing that the filing is authorized.					
6.	Inventorshi	p Statement					
	The in	ventorship for all the claims in this application is:					
	€	The same					
		Not the same. An explanation, including the ownership of the various claims at the time					
		last claimed invention was made					
		□ is submitted.					
		□ will be submitted.					
7.	Language						
	⇙	English					
		non-English					
		the attached translation is a verified translation. 37 CFR 1.52(d).					
8.	Assignment						
	ଁ ଅ	An assignment of the invention to SARSTEDT AG & Co.					
		is attached.					
		will follow.					

9. Certified Copy

Certified copy of application

Country Germany **Number** 19929665

Date 25 June 1999

from which priority is claimed

- □ is(are) attached.

10. Fee calculation

✓ A. Utility application

CLAIMS AS FILED

	No. Filed	Base No.	No. Extra	Rate	Basic fee
					\$690.00
Total claims	9	20	0	\$18.00	\$0.00
Independent claims	2	3	0	\$78.00	\$0.00
Mult. dep. claims	No	n/a	n/a	\$260.00	\$0.00

- □ Amendment canceling extra claims enclosed.
- Amendment canceling multiply dependent claims enclosed.
- \Box Fee for extra claims is not being paid at this time.

Filing Fee Calculation

\$690.00

□ B. Design application

(\$.00--37 CFR 1.16(f))

Filing fee calculation

\$00.00

□ C. Plant application

(\$490.00--37 CFR 1.16(g))

Filing fee calculation

\$00.00

11. Small Entity Statement(s)

Verified Statement(s) that this is a filing by a small entity under 37 CFR 1.9 and 1.27 is(are) attached

Filing fee calculation (50% of A, B, or C above)

12. Request for International-Type Search (37 CFR 1.104(d))

Please prepare an international-type search report for this application at the time when national examination on the merits takes place.

\$0.00

\$0.00

13.	Fee Payment							
	d	Not e	Not enclosed.					
		≰	No filing fee is to be paid at this time.					
		Enclo	-					
		□ basic filing fee						
			petition fee for filing by other than all the inventors or person on behalf of the inventor where inventor refused to sign or could not be reached	\$0.00				
			for processing an application with a specification in a non- English language	\$0.00				
				\$0.00				
			processing and retention fee	00.02				

14. Method of Payment of Fees

□ Check in the amount of \$0.00

Total fees enclosed

Charge Account 18-2025 for \$0.00. A duplicate of this form is attached.

fee for international-type search report

15. Authorization to Charge Additional Fees

- The Commissioner is hereby authorized to charge the following additional fees by this paper and during the entire pendency of this application to account 18-2025.
 - □ 37 CFR 1.16(a), (f), or (g) (filing fees)
 - □ 37 CFR 1.16(b), (c), or (d) (extra claims)
 - □ 37 CFR 1.16(e) (surcharge for filing the basic filing fee and/or declaration on a date later than the filing date of the application)
 - □ 37 CFR 1.17 (application processing fees)
 - 37 CFR 1.18 (issue fee at or before mailing of Notice of Allowance pursuant to 37 CFR 1.31(b))

16. Instructions As To Overpayment

- □ credit account 18-2025
- □ refund

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23 June 2000

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Application Information::

Title Line One:: SAMPLING TUBE AND METHOD OF MAKING SAME

Total Drawing Sheets:: 2 Formal Drawings?:: Yes

Application Type:: Utility

Docket Number:: 21543

Secrecy Order in Parent Appl.?:: No

Representative Information::

Representative customer number:: 535

Prior Foreign Applications::

Foreign Application One:: 19929665

Filing date:: 25 June 1999

Country:: Germany
Priority claimed:: Yes

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SAMPLING TUBE AND METHOD OF MAKING SAME

SPECIFICATION

FIELD OF THE INVENTION

The present invention relates to a sampling vessel of synthetic resin material, usually injection-molded thermoplastic, which can be used to hold biological samples as blood, serum or urine and to a method of making the sampling tube.

BACKGROUND OF THE INVENTION

Sampling tubes injection molded from thermoplastic synthetic resin material have been provided in the past as cylindrical vessels, open at opposite ends and provided with an intermediate bottom or well in which the sample is retained and which serves to allow even a small specimen to have sufficient depth to enable its removal by the pipette or needle.

A tube of this type, for example for use with conventional laboratory instruments, can be received in a rack provided with cavities dimensioned to receive the sampling tubes and can have a diameter of say 12 mm and a length of 75 mm.

Because of the recessed configuration of the intermediate bottom, the sampled material, e.g. blood, urine or serum, can be of sufficient depth to enable removal of the sample or part of the sample and the open end of the tube insures easy accessibility to the sample. Since the needle or pipette tip for

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extraction the sample does not have to reach to the end of the tube but merely into the well, usually conical, provided in the intermediate bottom or partition, there is little danger of damage to the needle.

The entire tube is usually produced by an injection molding process in one piece from the thermoplastic synthetic resin and circularly cylindrical walls extend upwardly from the well to form the mouth of the vessel and downwardly from the well to provide a bottom which can rest on a horizontal surface or on a support in the rack. The tube can be produced by injection molding in one piece through the use of two cores which define the hollow spaces of the tube above and below the well-forming intermediate bottom.

A problem with the method of manufacture used to date has been that the use of two cores, which must be withdrawn in opposite directions from the tube, has limited the configuration of the sample tube to one in which the walls extend vertically in both directions from the bottom or well.

This can be a drawback when the receptacle in which the tube is to be received has a hemispherical or curvilinearly concave surface on which the tube is to stand. Racks, stands or holders of this shape cannot stably receive the cylindrical bottom wall of a sampling tube of the type described fabricated with two cores.

One solution to this problem, of course, is to initially provide a sampling tube with a rounded bottom in which

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the sampled material is to be received, but this solution does not have the advantages of an intermediate bottom or well located above the lower end of the tube as described above. Another possibility, of course, is to assemble the sampling tube of two pieces, one of which forms the lower part and is rounded. This system has the disadvantage that it requires additional assembly steps and increases the fabrication costs, which may be substantial especially when the tubes are to be mass produced.

Other systems may utilize hangers or lips of the sampling tube which suspend the sampling tube in the rack or otherwise solve the problem of stability by retaining the sampling tube in other ways on the holders.

None of these approaches, however, has proved to be satisfactory.

OBJECTS OF THE INVENTION

It is, therefore, the principal object of the present invention to provide an improved sample tube, especially for biological samples such as blood, urine and serum, which is especially suitable for use in mechanized laboratory equipment, whereby drawbacks of earlier tubes are avoided.

Another object of this invention is to provide a sample tube for the purposes described which can rest in a concave holder without instability problems arising when the lower end of the tube is formed by a cylindrical wall.

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Another object of the invention is to provide an improved method of making a sample tube which satisfies the requirement for mass production and low cost and yet is capable of providing a tube which can be retained on a concave support.

SUMMARY OF THE INVENTION

These objects and others which will become apparent hereinafter are attained, in accordance with the invention in a sample tube which is formed in one piece with an intermediate bottom between upper and lower ends of the tube, vertical walls extending upwardly to the mouth of the tube and a lower wall extending to the bottom of the tube and a rounded bottom formed on the lower end of the tube.

According to the invention, the bottom end of the injection molded thermoplastic intermediate piece, previously provided with the well and the walls extending upwardly and downwardly from that well in the injection molding process, is thermally reformed by heating the bottom and simultaneously pressing a concave contour of a ram, complementary to the contour to be formed on the bottom of the tube, against the latter, thereby rounding upwardly the previously cylindrical bottom end of the tube.

The process of the invention thus involves, as a first step, the injection molding of an intermediate product which can correspond to the convention sampling tube previously described with its cylindrical wall extending from the intermediate bottom

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or well to the open end of the tube, the intermediate bottom itself which preferably tapers downwardly and is advantageously of conical configuration, and a lower cylindrical wall which extends from that intermediate bottom to the lower end of the intermediate product, all in one piece.

The second step of the process is the reshaping of the lower end of the intermediate product by thermally softening the lower end and pressing a shaping ram, plunger or stamp thereagainst which has the complementary contour of the shape to be imparted to the bottom of the tube.

The result, upon cooling, is a rounded bottom of the tube formed in one piece.

Of course, the invention also includes the sample vessel or tube formed in one piece of thermoplastic synthetic resin with cylindrical walls extending in opposite directions from the intermediate bottom but formed at the lower end with an inwardly turned portion directed toward the axis of the tube and preferably providing the rounded contour mentioned previously.

The point of the invention, of course, is that after formation of the intermediate product utilizing two cores by the injection molding process so that the intermediate bottom is provided in one piece with the walls of the tube, the cylindrical portion of the tube which is to constitute the bottom is thermally reformed by locally heating the bottom of the plastic tube intermediate product and shaping it with a contoured stamp or shaping surface to turn the outer edges of that cylindrical

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wall inwardly and permanently reshape the bottom. The rounded contour thus formed can be self-centering on the concave seats of conventional laboratory devices, racks or stands and need not precisely match the radius of curvature or contour thereof.

The fact that both the tube bottom and the seat are concave suffices to insure automatic centering. The result is a one piece sample tube with an intermediate well whose bottom has edges inwardly turned toward the axis.

Since the recesses or seats of conventional apparatus and racks, usually are hemispherical, in a specifically advantageous embodiment of the invention, the bottom of the tube has a convex curvature which can conform to a segment of a sphere.

The bottom of the tube, when reformed, can form a complete hemisphere or part thereof and or need not be completely closed and, indeed, according to the invention, an opening can be left in the bottom and merely the edges turned inwardly. The centering effect is nevertheless insured.

The geometric configuration of the bottom is not limited by the concavity of the shaping plunger and it can have a polyhedral, especially, tetrahedral, frustopyramidal, conical or frustoconical geometry depending upon the configuration of the supporting surface in the rack or stand. The tube itself need not be cylindrical but can be of a prismatic or polyhedral shape.

Preferably, the thermal reforming process is carried out at temperatures above the flow limit of the plastic utilizing

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a heated tool which is pressed axially against the bottom end of the intermediate product.

To protect the portions of the intermediate product which are not to be reshaped by the process from the effective temperature, especially upon heating of the bottom of the tube to a temperature above the flow limit of the plastic and to hold the tube during the reforming process, the tube can be engaged in an appropriate holder which can surround the tube immediately above the bottom portion to be reformed.

To prevent the tube from sliding in this holder, another member can press against the open end of the tube.

The holder preferably completely surrounds the tube and can be cooled. It is however also possible to engage the tube in an entirely conventional holder and to insulate that holder from the heated part of the apparatus.

BRIEF DESCRIPTION OF THE DRAWING

The above and other objects, features, and advantages will become more readily apparent from the following description, reference being made to the accompanying drawing in which:

FIG. 1 is a longitudinal section through a simple tube according to the invention and the apparatus for making same in a highly diagrammatic form; and

FIG. 2 is a longitudinal section through a prior art sample tube with an intermediate bottom which can also serve as the intermediate product for the method of the invention.

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SPECIFIC DESCRIPTION

FIG. 1 shows the apparatus of the invention, in highly diagrammatic form, for producing the sample tube of the invention. The latter, also seen in FIG. 1, is represented at 1 and has a cylindrical wall two extending in one axial direction from an intermediate bottom or well 5 of conical shape and another cylindrical wall 2' extending in the other direction. The walls 2, 2' and the intermediate bottom are molded in one piece from a thermoplastic synthetic resin material. The tube has an upper end or mouth 3 through which the sample is introduced and form which the sample is extracted, e.g. by a pipette inserted through the mouth 3 into the well formed by the conical bottom 5 which insures that even for a small amount of liquid sample, the sample will rise to a relatively high level in the well.

The bottom formed at the opposite end 4 of the tube has inwardly turned portions 7 extending toward the axis A of the tube and possibly reaching the axis or meeting at the axis to close the lower space 2a of the tube. Normally, however, in opening 2b is left in the bottom of the tube. The rounded bottom self centers on the seats normally provided in rats or laboratory equipment, simple collectors and simple distributors which operated with automatically pipettes or sample distributing tubes or needles. The cylindrical bottom 4 of the tube thus serves as a stand or foot while the open end 3 is usually closed by a screw or plug cap (not shown).

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In the production of the sample tube of the invention, an intermediate body is produced by the injection molding process (FIG. 2) with two cores 6 and 7 here illustrated in broken lines and which after the injection of the walls 2 and 2' and the partition 5 in one piece are withdrawn axially in opposite directions.

The intermediate product shown in FIG. 1 can then be engaged between the two parts 81, 82 of a holder embracing the tube 1 from opposite sides and composed of a thermally insulating material and/or composed of structures which are cooled. The clamp jaws 81 and 82 frictionally engage the cylindrical walls of the tube 1 and can be shaped to practically fully embrace the tube 1, leaving the top and bottom ends 3 and 4 freely.

At the top end 3, a third part of the apparatus, represented at 83 and forming an abutment to prevent movement of the tube 1 upwardly in the clamp 81, 82, is pressed against the tube end 3 in the direction of arrow B. This will prevent slip of the tube 1 in the friction clamp 81, 82.

In the illustration of FIG. 1, the abutment 83 has not yet engaged the intermediate tube 1.

According to the invention, the thus held intermediate tube 1, protected from heating except at its bottom 4, is engaged by a heated stamper or ram 9 provided with a heating element 12 shown as a resistance heater is pressed against the bottom 4 of the tube 1 in the direction of arrow C. The outer surface 91 and 92 of the stamp 9 are shaped complementarily to the shape to be

imparted to the bottom 4 and thus include a concavity 93 which can correspond to the spherical segmental shape of a seat adapted to receive the tube in a laboratory machine or a laboratory stand. The contact with the stamp causes the tube bottom 4 to be heated to a temperature above its softening point and preferably above the flow temperature of the thermoplastic synthetic resin, which can be any plastic conventionally used for the fabrication of biological sample tubes, and to flow to the shape imparted by the stamp 9. The edges of the bottom 4 are thereby turned inwardly along the stamp contour toward the axis A to impart the convex curvature 10 to the bottom of the tube. It is not necessary that a complete bottom be formed and it suffices to form a partial rounding of the bottom as shown in FIG. 1 by the solid lines 11 and 12 which represent a degree to which the bottom wall is turned inwardly. The stamp 9 is then withdrawn and the one piece contoured bottom sample tube is removed. When the sample tube is then mounted in a laboratory apparatus or rack, the rounded bottom automatically orients itself and thereby facilitates removal of a sample by a pipette or the like.

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I CLAIM:

A method of making a sample tube especially to
 receive a biological sample, comprising the steps of:

injection molding an intermediate tube in one piece with a cylindrical wall and an intermediate bottom spaced between ends thereof; and

heating an end of said intermediate tube and pressing edges of said end inwardly toward an axis of said intermediate tube to thermally reform said tube and provide at least a partial bottom for the sample tube.

- 2. The method defined in claim 1 wherein said intermediate bottom is given a conical shape during the injection molding thereof.
- 3. The method defined in claim 2 wherein the bottom of the sample tube is rounded by pressing a heated stamp thereagainst to cause said bottom of said sample tube to be shaped to a concavity of a concave recess of said stamp.
- 1 4. The method defined in claim 3 wherein the bottom of 2 said sample tube is only partly closed by said stamp.

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- 1 5. The method defined in claim 4 wherein said stamp
- 2 heats said intermediate tube to a temperature at least equal to
- 3 the flow temperature of a thermoplastic synthetic resin
- 4 constituting said intermediate tube.
 - 6. A sample tube composed in one piece of thermoplastic synthetic resin and having a cylindrical wall, an intermediate bottom between ends of the tube molded in one piece with said wall and inwardly turned portions at a bottom of the sample tube extending toward an axis of said sample tube.
 - 7. The sample tube defined in claim 6 wherein said intermediate bottom is of conical shape.
 - 8. The sample tube defined in claim 7 wherein the bottom of said sample tube is rounded and is outwardly convex.
 - 9. The sample tube defined in claim 8 wherein the bottom of said sample tube is only partly closed.

ABSTRACT OF THE DISCLOSURE

A sample tube for injection molded with two cores in one base with an intermediate bottom forming a well for receiving the biological material. In a second stage, the bottom edge of the cylindrical wall is heated and turned inwardly to form preferably a rounded bottom of complementary contour to a stamp applied thereagainst in a thermal reforming operation.

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